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VIA FACIMILE

May 25, 2007

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Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Proposed COMAR 10.24.05 - Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery

Dear Dr. Neumann:

This letter sets forth the comments of MedStar Health on the above-referenced proposed regulations (the "Proposed Regulations").

PRELIMINARY MATTERS

Inclusion of Documents in the Public Record:

The Commission has previously received correspondence from MedStar Health, as well as from other sources, regarding the proposed C-PORT study. It is requested that this previous correspondence be included in the public record, if it has not already been made a part thereof. Specifically, it is requested that the following correspondence be included in the public record:

- Letter dated April 16, 2007 from Lyndon L. Bailey, President of Mended Hearts, Chapter 168 to Gail Wilensky, Ph.D., Vice-Chair Maryland Health Commission
- Letter dated January 12, 2007 from Barry F. Rosen to Rex W. Cowdry, M.D.
- All reports of the Data and Safety Monitoring Board with respect to the ongoing C-PORT Study

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Reservation of Rights:

While we have previously communicated that, we believe that the C-PORT elective PCI study should not move forward for ethical and other reasons, we are nevertheless taking this opportunity to comment on the Proposed Regulations. However, these comments should not be construed as an admission that the C-PORT elective PCI study should move forward in Maryland or, that our concerns about the ethical issues of the study have been resolved. We reserve the right to further challenge the study.

Overview of MedStar Health:

MedStar Health is a community-based healthcare organization, including seven major hospitals in the Baltimore/Washington area. These hospitals, which include both teaching and community facilities, are Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, and Union Memorial Hospital in Baltimore, and Washington Hospital Center, Georgetown University Hospital and National Rehabilitation Hospital in Washington, D.C. Both Union Memorial Hospital and Washington Hospital Center offer a full range of cardiac care services, including open-heart surgery and angioplasty services. Union Memorial's cardiac program is the fastest growing program in Baltimore, and Washington Hospital Center is one of the largest and most highly regarded providers of cardiac services in the region.

COMMENTS

These comments are intended to address the Commission's stated goal of achieving "strong volumes, cost effectiveness and improvement in geographic access" in the context of the proposed research study. For the reasons stated in previous correspondence from MedStar on this issue, our suggestions are intended to ensure informed consent for potential study participants, as well as minimize the impact on existing providers to the maximum extent possible. For each comment, the language of the applicable section is included in bold, followed by a brief statement of the proposed change in italics, and then a discussion of the reasons for the proposed change. At the conclusion of this comment section are additional general comments about the regulations.

10.24.05.02.C

The Commission may grant a waiver from Policy 5.0 of COMAR 10.24.17.04E for no more than six (6) hospitals without on-site cardiac surgery to perform the non-primary PCI as part of the C-PORT study.

The number of waivers should be allocated based on region, and each region should have only one waiver slot. Further, for the Baltimore Metropolitan Region and the Washington

Metropolitan Region, where access to PCI is not a problem, substantial additional justification must be provided to grant exceptions to this rule.

The Commission and the staff have previously expressed the view that a primary reason for allowing expansion of elective PCI is to improve the ability of rural hospitals to perform primary PCI. It therefore follows that the majority of waiver sites for elective PCI should be granted to rural hospitals. Moreover, in the metropolitan regions, where the vast majority of residents are within 20-30 minutes of a heart center, there must be compelling justification for exposing patients to additional risk with no corresponding clinical benefit. The suggested requirement assures an adequate study sample size, maximizes elective PCI availability in rural areas, but minimizes excessive costs.

10.24.05.03.B(1)

A hospital without on-site cardiac surgery in the Metropolitan Baltimore or Metropolitan Washington regional service area may file an application for a waiver to perform non-primary PCI services within the C-PORT study if, at the time of application, the hospital has a 2-year waiver to perform primary PCI.

An additional requirement for a hospital in these regions to be eligible to file an application should be that the applicant is at least five (5) miles from an existing open-heart surgery center.

Many of the hospitals in the Metropolitan Baltimore or Washington regions are located very near existing heart centers. There is no justification for allowing them to perform elective PCI. Further, for the hospitals within these regions that currently perform primary PCI, these hospitals typically draw their interventional cardiologists from the same pool of interventionalists that serve the nearby tertiary hospitals, so allowing elective PCI at these centers will not account for any significant improvements in access to the primary PCI services at these hospitals. Competing for the same pool of scarce staff and physician resources will increase cost substantially. The five-mile requirement, therefore, should help assure that geographic access is improved, and may help to minimize the cost impact from programs that share the same staff.

10.24.05.04A(2)(b)

Physician Resources. An applicant must document that it has or will recruit adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists...

Three interventional cardiologists will leave no room for illness, vacation or conflicting schedules. Accordingly, requiring 4 or 5 interventional cardiologists would be more appropriate and is *essential for 24/7 coverage.*

Staff shortages and increased competition for scarce staff are likely to result from expanding elective PCI services. While increasing the number of required interventionalists will admittedly

add to this pressure, the reality is that requiring only three interventionalists will lead to insufficient coverage.

10.24.05.04.A (3)

In determining whether to grant a waiver application, the Commission may consider appropriate factors, including:

(a) An applicant's potential to improve the geographic distribution of cardiovascular services;

(b) An applicant's potential to increase access to PCI services for minorities and medically underserved populations;

(c) An applicant's ability to serve as a site for conducting research;

(d) An applicant's demonstration of successful and timely acquisition of follow-up data on primary PCI patients; and

(e) An applicant's current performance under its primary PCI waiver.

*The Commission should be **required** to consider the above factors in determining whether to grant a waiver.*

*In addition to the above cited factors, the Commission should be **required** to consider whether granting a waiver application will: 1) have an adverse impact on existing elective PCI providers; 2) raise the cost of health care in the State; or 3) cause or contribute to a shortage of the highly trained staff necessary to run catheterization labs.*

The factors set forth in this section either: 1) speak to the very reasons the staff and the Commission have cited as allowing the study to proceed (factors a and b); or 2) speak to whether the study will be successful (factors c, d, and e). Therefore, we suggest changing the first sentence to require that the factors identified be considered.

*We also recommend adding as (f), "Before granting any waivers, the Commission should be **required** to consider whether the C-PORT study, based on its historical performance, is likely to produce reliable results" and as (g), "Before granting an waivers, the Commission should be **required** to project whether there is sufficient funding to sustain the study."*

In other states, the C-PORT study has been enrolling patients for a year and half. Data for this year and half period (which represents almost 2/3 of the projected study period of 28 months) already indicates that the study may not produce reliable results. For instance, the actual enrollment rate per hospital is approximately 127 patients annualized versus the study's anticipated 200 patients. In addition, the study, originally predicted to last for 28 months (which would be an end date of mid-2008), is now projected to run much longer, resulting in significant additional costs. However, there is no projection as to where the necessary additional funding will come from.

In his recommendation, Dr. Cowdry notes that the cost of the study is likely to be approximately four million dollars, and stated that the ability to meet the costs of the study is a concern. For

that reason he states that funding should be closely monitored in the future. However, presumably the hospitals that have been participating in the study since early 2006 have already made their 2-year contributions to the study, which were most likely based on the original study's cost projection of $34,000 per year and not the revised study's projected costs of $52,500 per year. It should therefore be a simple matter to determine as of today, how much of the projected $4 million in funding the study has actually received.

10.24.05.05.A

A waiver to perform non-primary PCI issued by the Commission will expire on the earlier of:

(1) Two years from the date on which the Waiver was first issued;

(2) The date patient accrual into the C-PORT study ends;

(3) A finding made by the Commission that the C-PORT study is not accruing patients at an acceptable rate; or

(4) A finding by the Commission that the C-PORT study is unlikely to produce reliable results to guide public policy.

With respect to (1), waivers should be granted for a maximum of one year, so that the Commission may monitor whether the applicant is meeting the volume and other requirements of the study and the regulations.

Granting only one-year waivers would be consistent with the current process for granting initial waiver applications to perform primary angioplasty. It would also provide a definitive timeframe and process for a re-evaluation of the study's overall experience and an assessment of the continuing likelihood that the study will produce reliable results.

With respect to (3) and (4), as stated above, these findings should be made by the Commission before granting any waiver applications, in addition to being made at the end of the one year waiver period.

Other Comments on the Proposed Regulations:

The following requirements should be added to the draft regulations.

1) The Proposed Regulations should allow for comments on applications by interested parties and participating entities.

The Commission should be required to consider adverse impact on existing providers and the cost implications of granting a waiver to participate in the study. Accordingly, the Commission should allow interested parties to comment on applications, particularly to demonstrate the impact that granting the wavier will have on the interested party's operations and ability to provide quality medical services. Likewise, the Commission should take comments from participating entities such as payors, particularly with respect to increased costs, which may result from granting a wavier.

The Commission should consider the comments of interested parties and participating entities even though the waivers that will be granted are only to participate in the study and are, theoretically, temporary in nature. The Proposed Regulations provide that the Commission may extend a waiver beyond the currently proposed 2-year period. Because the study's lead researcher is already predicting that the study may last twice as long as was initially projected, it is possible that Maryland waivers may extend well beyond 2 years. This, coupled with the 1 to 3 randomization scheme of the study (for every 4 patients, 3 patients who ordinarily would have been diverted to a nearby heart center will remain at the waiver hospital) could lead to significant adverse impact on existing providers, as well as increased costs to payors, despite the "temporary" nature of the waiver.

2) Because the criteria for granting primary PCI waivers is used in part as the basis for granting waivers for elective PCI, the Commission should strictly enforce the primary PCI criteria.

In 2006, the Commission granted several Baltimore Metropolitan and Washington Metropolitan region hospitals conditional one-year waivers to perform primary angioplasty. Even though many of these hospitals had been performing primary PCI for several years (in the original C-PORT study), the Commission did not grant these hospitals two-year waivers because of their failure to meet one or more of the criteria established for primary waiver hospitals, such as door to balloon time and volume requirements. Most of these hospitals have filed or are likely to file applications to renew their primary waivers. The Commission should strictly enforce the primary PCI criteria and refuse to renew the waiver of any hospital, which does not meet the criteria.

3) The Commission should also require documentation of the projected incremental costs (for equipment, transportation and staffing, including all costs related to contracts and other arrangements with physicians related to physician coverage) to the applicant to participate in the study.

The Commission has previously raised many of these concerns as real concerns regarding the de-centralization of angioplasty services in the State, including the cost of the proliferation of angioplasty programs. Selection of certain waiver sites will have a definite negative impact on costs to the health system and on existing heart centers. Pulling volume from a strong heart center to bolster volume at a nearby community hospital will only serve to decrease overall quality of care in the State by creating a pool of mediocre providers versus having a select number of centers of excellence. Further, evidence establishes that, due to economies of scale, the cost to perform elective PCI is significantly greater ($6,084 per procedure in 2002) at low volume hospitals than the cost at high volume hospitals. Finally, there is a finite number of highly qualified interventional cardiologists and staff necessary for performing PCIs and running catheterization labs. Broadening the field of hospitals providing such services will only serve to create bidding wars for these physicians and staff.

4) Last, before granting waivers, the Commission should be assured that each participating facility has a sound plan for ensuring that participants understand the goals of the study, the risk of participating in the study, and are advised of less risky treatment alternatives available to them.

Given the finding of the Commission's Advisory Committee on Outcome Assessment in Cardiovascular Care Interventional Cardiology Subcommittee that there are no clinical benefits to be derived for patients who participate in the study, it is important that those who are being asked to participant in the study know this. Also, given that preferences are contemplated in the selection criteria for those programs that expand access to minority populations, many who are currently underserved, it is acutely important that the study population is balanced in terms of representation and not overly represented by minorities. Specific efforts should be made to ensure minority populations, many who may not have personal primary care providers be informed of the options for care available to them other than through the study.

CONCLUSION

MedStar Health respectfully asserts that implementing the foregoing comments will result in a research project that better adheres to amendments to Dr. Cowdry's recommendation that were proposed by Commissioner Row and adopted in the draft regulations - namely having the Proposed Regulations address the achievement of "strong volumes, cost effectiveness, and improvement in geographic access."

Thank you.

Sincerely,

Michael C. Rogers
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cc: Kenneth A. Samet
Harrison Rider
Mike Ryan